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February 19, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the ACC's HPV Test Plan for the Higher Olefins Category

Dear Administrator Whitman:

The following comments on the American Chemistry Council (ACC) test plan for the higher olefins category are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

The ACC test plan for the higher olefins reflects a thoughtful approach to the development of robust summaries and test plans. The ACC intends to draw on existing data and to correlate systematic structural changes with changes in toxicity. In addition, we applaud their application of ECOSAR modeling to estimate aquatic and fish toxicity values. This approach is especially appropriate for the highly insoluble compounds in this group.

While we appreciate the ACC's efforts, the organization does not take this systematic analysis far enough. The ACC proposes to conduct an OECD 422 combined repeat/reproductive/developmental toxicity test with a C6 internal olefin stream and an OECD 421 combined reproductive/developmental test with a C18 internal olefin. The ACC fails to provide adequate justification for these additional tests, as existing information is sufficient for filling data gaps under the HPV program. Existing information confirms and supports the ACC's hypothesis that the position and number of double bonds in complex olefins have little effect on their toxicity.

The ACC has developed a scientifically justifiable category for many mixtures. Higher olefins have a variety of commercial uses. The category satisfies the criteria described in the EPA guidance document because they are discrete chemicals with incremental changes and the same functional groups. The category includes olefins with even and odd carbon numbers, alpha and internal olefins, and linear and branched olefins. (Draft Guidance on Developing Robust Summaries, October 22, 1999, http://www.epa.gov/chemrtk/robsumgd.htm).

Many animal studies have already been conducted with various alkenes, including repeat-dose toxicity studies of compounds similar to those proposed for additional combination repeat-dose/neuro/repro/developmental toxicity tests. Sufficient

information exists to characterize the low toxicity of the members of this category. Existing information indicates that the placement of the double bond or linear versus branched chains does not alter the toxicity profile. Some reproductive and developmental studies have also already been conducted with structurally similar chemicals.

The ACC could draw on information from its own robust summaries of propylene streams and C5 non-cyclics categories, as well as the American Petroleum Institute's gasoline and fuel oil categories to test its hypothesis about the relationship between structure and toxicity, without the need for additional tests on animals. Also, a great deal of work has been done by the ATSDR on the toxicity of long-chain hydrocarbons in its evaluation of the toxicity of total petroleum hydrocarbons.[1] The ATSDR's work and the accumulation of the other studies on the subject show that these types of compounds are generally non-toxic and non-mutagenic, with any toxic effects mainly due to physicochemical properties. Observed toxicological effects in previous studies generally only occur at doses greater than 100 mg/kg/day for lower molecular weight compounds, and greater than 1000 mg/kg/day for higher molecular weight compounds. With the observed low toxicity of these compounds and clear understanding of their toxicity, it is appropriate to draw on existing information to satisfy the HPV endpoints, rather than conduct additional testing in order to satisfy the EPA's check-the-box approach.

Thank you for the opportunity to comment and we look forward to discussing these tests further with the EPA and the ACC. I can be reached at 757-622-7382, ext. 1304.

Sincerely,

Jessica Sandler, MHS
Federal Agency Liaison

[1] ATSDR 1999. Toxicological Profile for Total Petroleum Hydrocarbons Found at: http://www.atsdr.cdc.gov/toxprofiles/tp123.html.